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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/486,247	05/25/2000	TERENCE N. DEAR	8484-081-999	3571

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EXAMINER

FRONDA, CHRISTIAN L

ART UNIT	PAPER NUMBER
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1652

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DATE MAILED: 12/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/486,247

Applicant(s)

DEAR ET AL.

Examiner

Christian L Fronda

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8,9 and 16-23 is/are pending in the application.
- 4a) Of the above claim(s) 19,20,22 and 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 18, 19, 16-18, 21 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

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DETAILED ACTION

1. In the Response to Office Action Pursuant to 37 C.F.R. 1.111 dated February 21, 2002 (Paper No. 16), Applicants have amended claims 8, 9, 16, and 17 and added new claims 18-23.

Election/Restrictions

2. Newly submitted claims 19, 20, 22, and 23 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: as stated in the Office Action dated 7/11/01 (Paper No. 9), the originally filed inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. New claims 19, 20, 22, and 23 correspond to the invention of Group I. The special technical feature of the claimed invention is a protease-related protein comprising an amino acid sequence differing by one or more amino acids from the sequence depicted in FIGURE 1. However, Tindall et al. teach a human prostate-specific glandular kallikrein (hK2) which differs by one or more amino acids from the claimed amino acid sequence depicted in FIGURE 1 (see entire patent and SEQ ID NO:10 attached to Office Action dated 7/11/01 (Paper No. 9)).

Since Applicants have not contributed a special technical feature over the prior art in view of the teachings of Tindall et al., claims 19, 20, 22, and 23 do not have a single general inventive concept and therefore lack unity of invention. Accordingly, claims 19, 20, 22, and 23 are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 19, 20, 22, and 23 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

3. Claims 8, 9, 16-18, and 21 are under consideration in this Office Action. New rejections are presented in the instant Office Action.

Claim Rejections - 35 U.S.C. § 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and

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requirements of this title.

5. Claims 8, 9, 16-18, and 21 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well established utility.¹

Applicants disclose the nucleotide sequence of SEQ ID NO: 1, the deduced amino acid sequence of the protein encoded as SEQ ID NO: 2, and assigned the protein of SEQ ID NO: 2 as a “protease-relate protein”. However, the specification does not disclose the **specific** function of the protein of SEQ ID NO: 2 or its specific relationship to any disease. While applicants have disclosed that the protein of SEQ ID NO: 2 is characterized as having homologies with a protease of the kallikrein family, homology is not a disclosure of how to use the protein or polynucleotide encoding the protein of SEQ ID NO: 2. The specification does not explicitly state that homology to a reference protein known in the prior art is a disclosure that the claimed protein has the properties and biological function of the reference protein relied upon.

Furthermore, although the specification teaches that when the *whn* gene product is absent then the *Ha3* and *CK15* are underexpressed and the polynucleotide encoding the PVP is overexpressed, such correlation does not indicate any causal relationship where overexpression of PVP promotes loss or lack of hair.

Substantial utility is one that provides a specific benefit in currently available form at the time of filing of the invention. However, the main utility of the nucleic acid and protein is to carry out further research to identify the biological function and possible diseases associated with the protein. Utilities that require or constitute carrying out further research to identify or reasonably confirm a specific use are not substantial utility and do not provide a specific benefit. Thus, the claimed invention has no specific or substantial asserted utility.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 8, 9, 16-18, and 21 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above in the rejection of claims 8, 9, 16-18, and 21 under 35 U.S.C. 101, one skilled in the art clearly would not know how to use the claimed invention.

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In addition, claims 8, 9, 16, 17, and 18 encompass any nucleotide sequence which hybridizes to SEQ ID NO: 1 at 20°C below the DNA melting which is not enabled by the specification. Factors to be considered in determining whether undue experimentation is required, are summarized In re Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The specification provides guidance for screening and searching for the claimed invention which **is not guidance for making the claimed invention**. In order to make the claimed invention one of ordinary skill in the art must perform an enormous and undue amount of experimentation since the specification does not teach the specific structural/catalytic amino acids and the structural motifs essential for protein activity/function which cannot be altered. Such experimentation entails screening and searching a vast number of polynucleotides “hybridizes to SEQ ID NO: 1 at 20°C below the DNA melting” and determining whether the polynucleotide encodes the claimed “protease-related protein”.

The experimentation involved to make the claimed invention is well outside the realm of routine experimentation and predictability in the art of success in determining whether the resulting polypeptide has activity is extremely low since no information is provided by the specification regarding the specific catalytic/structural amino acids and the structural motifs essential for enzyme/protein structure and activity/function which must be preserved.

Furthermore, since there is no in vivo working examples in the specification as filed to demonstrate the “negative regulation of the keratinization of hair” by administering the claimed “protease-related protein”, it is not clear that the claimed method is enabled. In re wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988), the decision of the court indicates that the more unpredictable the area is, the more specific enablement is necessary. In view of the quantity of experimentation necessary, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take an undue amount of experimentation for one skilled in the art to practice the claimed invention.

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 8, 9, 16-18, and 21 are rejected under 35 U.S.C. 112, second paragraph, as being

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indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 8, 9, 18, 21, the phrase "a protease-related protein" renders the claim indefinite because the meaning of the phrase is not known and it is not known when a protein is or is not related to a protease. Applicants' arguments filed 2/21/2002 have been considered but are not persuasive since the limitations of the claimed protein having homology to a protease of the kallikrein family and having protease activity are not recited in the instant claims. Thus, one of skill in the art cannot determine the metes and bounds of the claimed invention. Claims 9, 16, and 17 which depend from claims 8, 9, or 18 are also rejected because they do not correct the defect of claims 8, 9, or 18.

Claims 8, 16, and 17 are vague and indefinite because the specific hybridization conditions under which the claimed nucleotide sequence hybridizes to "SEQ ID NO:1 at 20°C below the DNA melting" are not known and not recited and the meaning of the phrase "below the DNA melting" is not known.

In claims 16 and 17, the phrase "having a different nucleotide composition due to the degenerated genetic code" renders the claim indefinite because the meaning of the phrase is not known and the specific nucleotide sequence claimed is not known or recited.

Amending the claim to recite that the nucleotide sequence encodes SEQ ID NO: 2 may overcome this rejection.

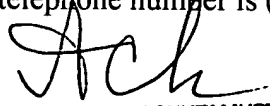
10. Claims 8, 9, 16-18, and 21 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: method steps for indicating whether administration of the protease-related protein results in the negative regulation of the keratinization of hair and the end-point of the method.

Conclusion

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. The fax phone number for this Group is (703)308-0294. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.
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